EcoCardioChirurgia®

CORSO MONOGRAFICO

9 e 10 aprile 2015

MILANO

LA STENOSI VALVOLARE AORTICA E L'INSUFFICIENZA MITRALICA

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LA STENOSI VALVOLARE AORTICA E L'INSUFFICIENZA MITRALICA

"QUANDO LA CORRETTA TERAPIA DELLA STENOSI NON E' LA TAVI"

La terapia con la sola valvuloplastica

In quali pazienti è preferibile alla TAVI e per quali ragioni ?

Cenni di tecnica

MAURIZIO ORNAGHI

Responsabile

U.O.S. Emodinamica

Ospedale Bassini

Cinisello Balsamo (MI)

i miei conflitti di interesse

ASTRA
ZENECA

L’infinito dentro me
Antonio Nunziante
2006

I PZ CON VALVULOPATIA RICEVONO UN TRATTAMENTO IN ACCORDO CON LE LG ?

A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease

Bernard Iung[a*], Gabriel Baron[b], Eric G. Butchart[c], François Delahaye[d], Christa Gohlke-Bärwolf[e], Olaf W. Levang[f], Pilar Tornos[g], Jean-Louis Vanoverschelde[h], Frank Vermeer[i], Eric Boersma[j], Philippe Ravaud[b], Alec Vahanian[a]

...nt, Bichat Hospital, AP-HP, Paris, France
...tistic, and Clinical Research Department, Bichat Hospital, AP-HP, Paris, France
...rtment, University Hospital, Wales, Cardiff, UK
...nt, Hopital Cardiologique, Lyon, France
...nt, Heart Centre, Bad Krozingen, Germany
...rtment, St. Elizabeth Hospital, Trondheim, Norway
...nt, Vall d'Hebron Hospital, Barcelona, Spain
...y, Catholic University of Louvain, Brussels, Belgium
...s Roermond, Netherlands
...dam, Netherlands

...revised 7 March 2003; accepted 12 March 2003

31.8% did not undergo intervention, despite NYHA class III/IV symptoms

KEYWORDS
Valvular heart disease;
Echocardiography;
Cardiac surgery

Aims To identify the characteristics, treatment, and outcomes of contemporary patients with valvular heart disease (VHD) in Europe, and to examine adherence to guidelines.
Methods and results The Euro Heart Survey on VHD was conducted from April to July 2001 in 92 centres from 25 countries; it included prospectively 5001 adults with moderate to severe native VHD, infective endocarditis, or previous valve intervention. VHD was native in 71.9% of patients and 28.1% had had a previous intervention. Mean age was 64±14 years. Degenerative aetiologies were the most frequent in aortic VHD and mitral regurgitation while most cases of mitral stenosis were of rheumatic origin.
Coronary angiography was used in 85.2% of patients before intervention. Of the 1269 patients who underwent intervention, prosthetic replacement was performed in 99.0% of aortic VHD, percutaneous dilatation in 33.9% of mitral stenosis, and valve repair in 46.5% of mitral regurgitation; 31.7% of patients had ≥1 associated procedure. Of patients with severe, symptomatic, single VHD, 31.8% did not undergo intervention, most frequently because of comorbidities. In asymptomatic patients, accordance with guidelines ranged between 66.0 and 78.5%. Operative mortality was <5% for single VHD.
Conclusions This survey provides unique contemporary data on characteristics and management of patients with VHD. Adherence to guidelines is globally satisfying as regards investigations and interventions.

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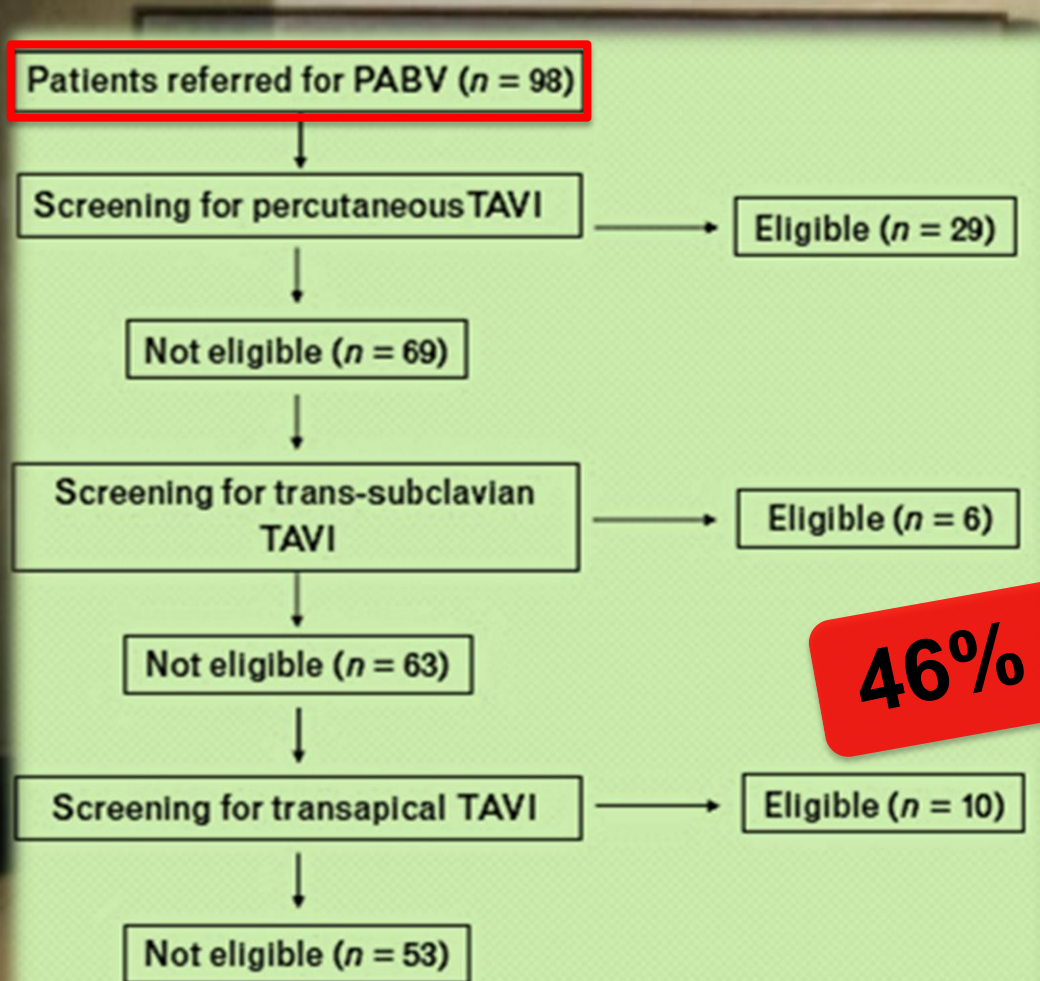
- 92 hospitals from 25 countries
- 5,001 patients from April-July, 2001

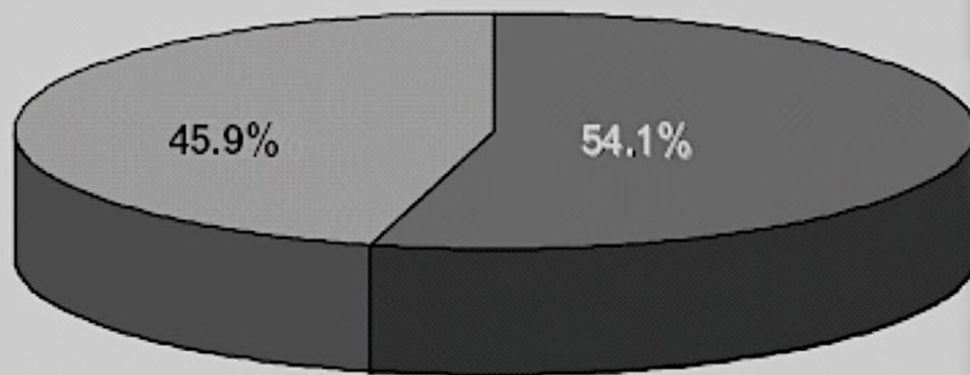
How many patients with severe symptomatic aortic stenosis excluded for cardiac surgery are eligible for transcatheter heart valve implantation?

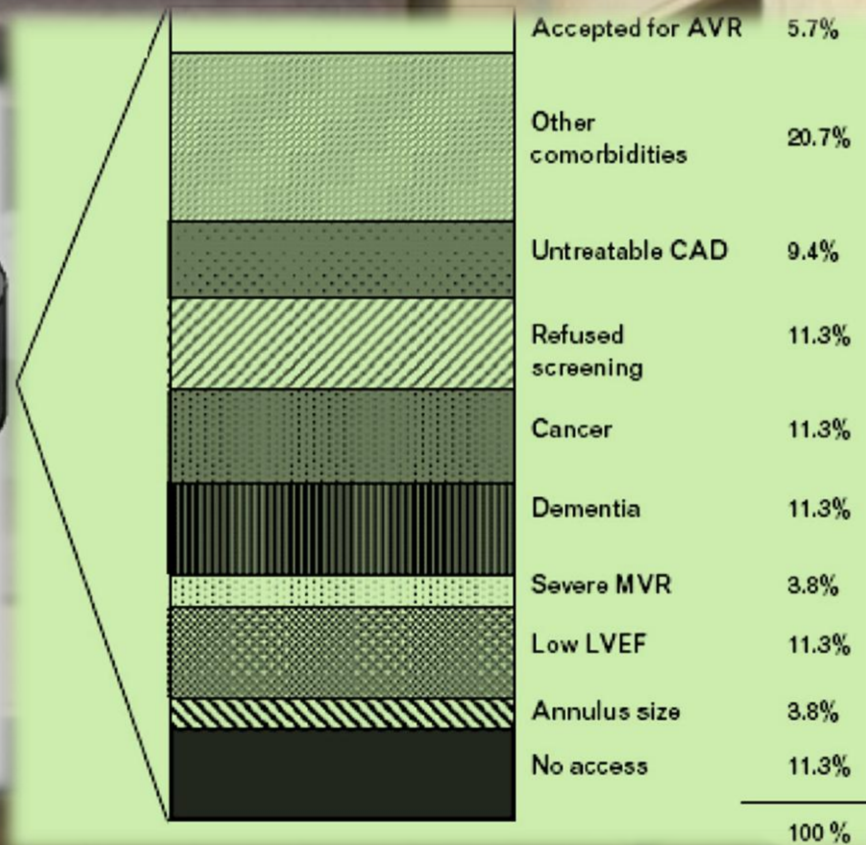
Francesco Saia[a], Cinzia Marrozzini[a], Gianni Dall'Ara[a], Vincenzo Russo[b], Sofia Martìn-Suàrez[c], Carlo Savini[c], Paolo Ortolani[a], Tullio Palmerini[a], Nevio Taglieri[a], Barbara Bordoni[a], Emanuele Pilato[c], Roberto Di Bartolomeo[c], Angelo Branzi[a] and Antonio Marzocchi[a] J Cardiovasc Med 2010



How many patients with severe symptomatic aortic stenosis excluded for cardiac surgery are eligible for transcatheter heart valve implantation?

Francesco Saia[a], Cinzia Marrozzini[a], Gianni Dall'Ara[a], Vincenzo Russo[b], Sofia Martìn-Suàrez[c], Carlo Savini[c], Paolo Ortolani[a], Tullio Palmerini[a], Nevio Taglieri[a], Barbara Bordoni[a], Emanuele Pilato[c], Roberto Di Bartolomeo[c], Angelo Branzi[a] and Antonio Marzocchi[a]





Cosa aspettarci dalla BAV ?

- **Alto successo procedurale 98%**
- **Bassa incidenza di complicanze**

- Significativo miglioramento dei sintomi e della classe funzionale

(1-2 classi NYHA)

- ***modesto incremento area valvolare 0.3 mm^2***
- **riduzione gradiente transvalvolare 50%**

EUROPEAN SOCIETY OF CARDIOLOGY®
European Heart Journal (2012) 33, 2451–2496
doi:10.1093/eurheartj/ehs109
ESC/EACTS GUIDELINES

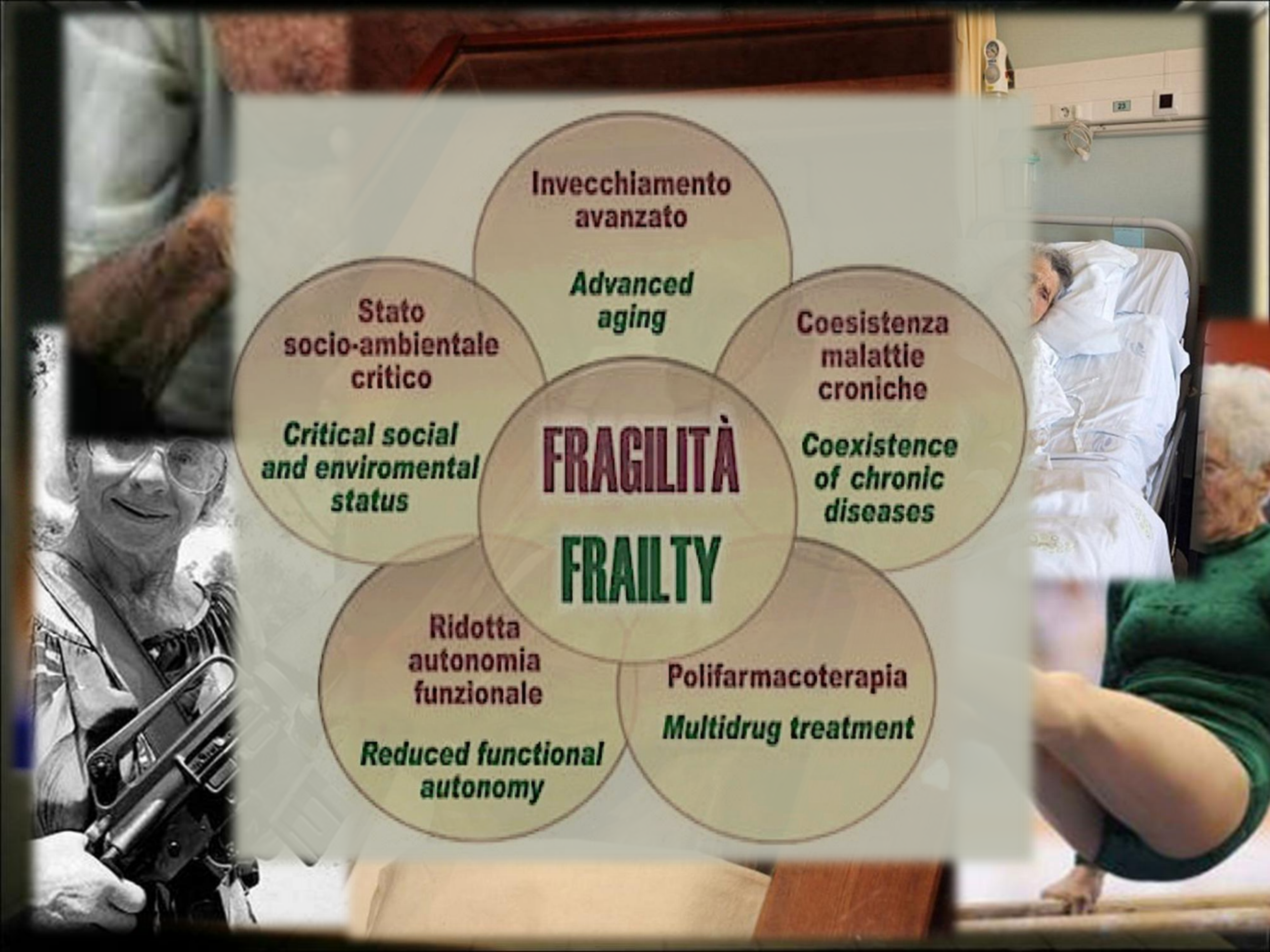
Guidelines on the management of valvular heart disease (version 2012)

5.4.2 Indications for balloon valvuloplasty

- *Bridge alla chirurgia in pz emodinamicamente instabili*
  (classe IIB, livello evidenza C)
  - **transitoria controindicazione a AVR o TAVI**
    (infezioni, emorragia, etc)

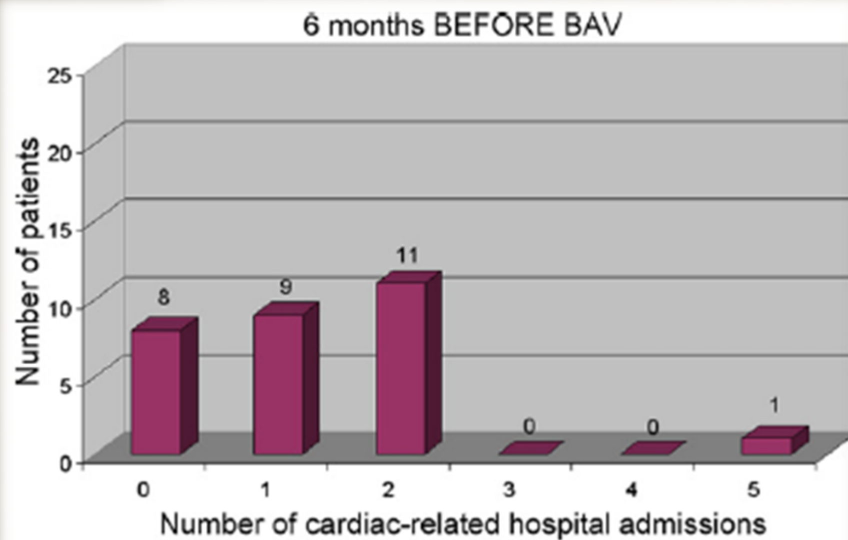
- ***Pz con SAo severa che devono essere sottoposti a chirurgia maggiore*** *NON CARDIACA* ***urgente***
  (classe IIB, livello evidenza C)

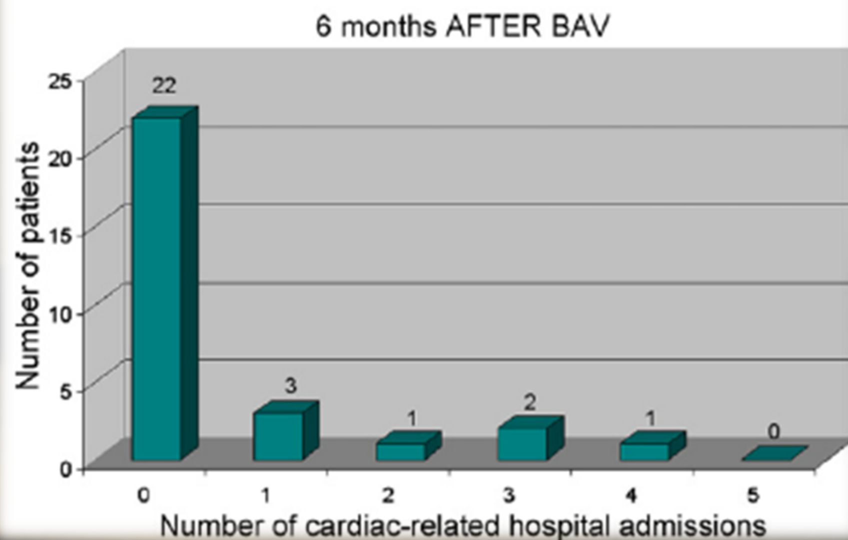
- **come terapia palliativa in casi selezionati quando la chirurgia è controindicata** ***(severe comorbilità)*** **e la TAVI non è un'opzione**


Invecchiamento avanzato
Advanced aging
Stato socio-ambientale critico
Critical social and enviromental status
Coesistenza malattie croniche
Coexistence of chronic diseases
FRAGILITÀ
FRAILTY
Ridotta autonomia funzionale
Reduced functional autonomy
Polifarmacoterapia
Multidrug treatment

BAV come terapia palliativa

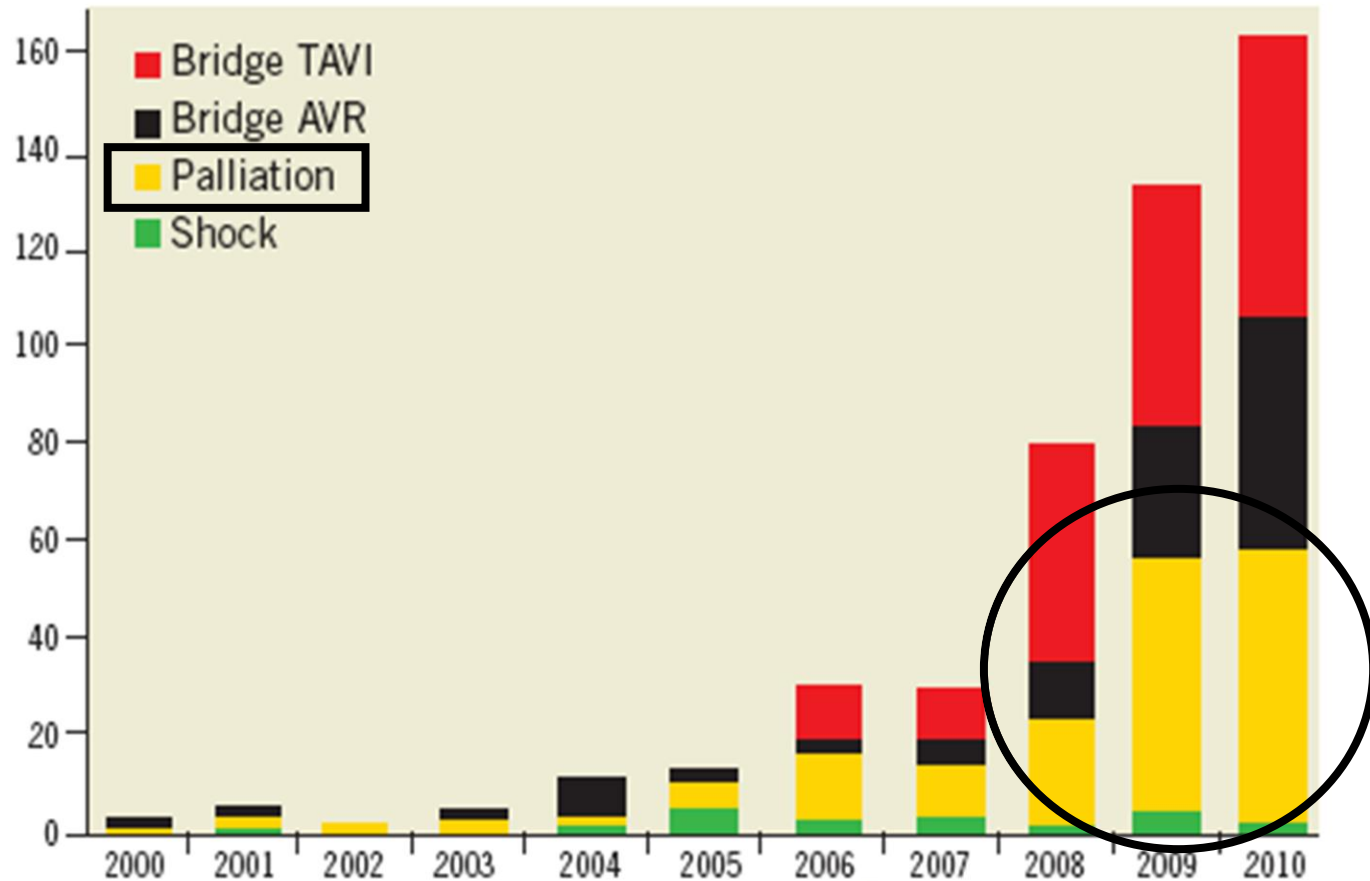
ACY et al. *Heart, Lung and Circulation* 2008;17:468–474





Emerging indications, in-hospital and long-term outcome of balloon aortic valvuloplasty in the transcatheter aortic valve implantation era

Francesco Saia[1]*, MD, PhD; Cinzia Marrozzini[1], MD; Cristina Ciuca[1], MD; Paolo Guastaroba[2], MSc; Nevio Taglieri[1], MD; Tullio Palmerini[1], MD; Barbara Bordoni[1], MD; Carolina Moretti[1], MD; Gianni Dall'Ara[1], MD; Angelo Branzi[1], MD; Antonio Marzocchi[1], MD



EuroIntervention 2013;8:1388-1397

euro PCR 2012 YEAR OF THE TEXTBOOK

When should we use stand-alone balloon valvuloplasty in the TAVI era?

Consensus

Dominique Himbert
CHU Bichat-Claude Bernard, AP-HP

PCR EAPCI EUROPEAN SOCIETY OF CARDIOLOGY EACTS

When should we use stand-alone balloon valvuloplasty in the TAVI era?

Consensus

BAV come "BRIDGE"

a potenziali ulteriori interventi

(AVR o TAVI)

- TRIAL TERAPEUTICO

in pz con COMORBILITA' confondenti

- *PROCEDURA RESCUE*

in pz con condizioni cliniche instabili, minacciose per la vita

When should we use stand-alone balloon valvuloplasty in the TAVI era?

Consensus

Dominique Himbert
CHU Bichat Claude Bernard, AP HP

BAV come "BRIDGE"

a potenziali ulteriori interventi (AVR o TAVI)

TRIAL TERAPEUTICO

- *Per determinare il contributo della stenosi aortica ai sintomi*
  (differenziare il contributo della patologia valvolare e/o della malattia polmonare alla dispnea)

- **Per aiutare il recupero del VS in pz con severa disfunzione ventricolare secondaria alla SAo**
  - **aiutando nel "bridge " alla selezione verso AVR/TAVI**
  - **agendo come bridge al trattamento, riducendo i rischi del trattamento definitivo**

Recovery After Balloon Aortic Valvuloplasty in Patients With Aortic Stenosis and Impaired Left Ventricular Function: Predictors and Prognostic Implications

J INVASIVE CARDIOL 2013;25(5):235-241

Joelle Kefer, MD, PhD, Jean-Marie Gapira, MD, Sophie Pierard, MD, Christophe DeMeester,
Olivier Gurne, MD

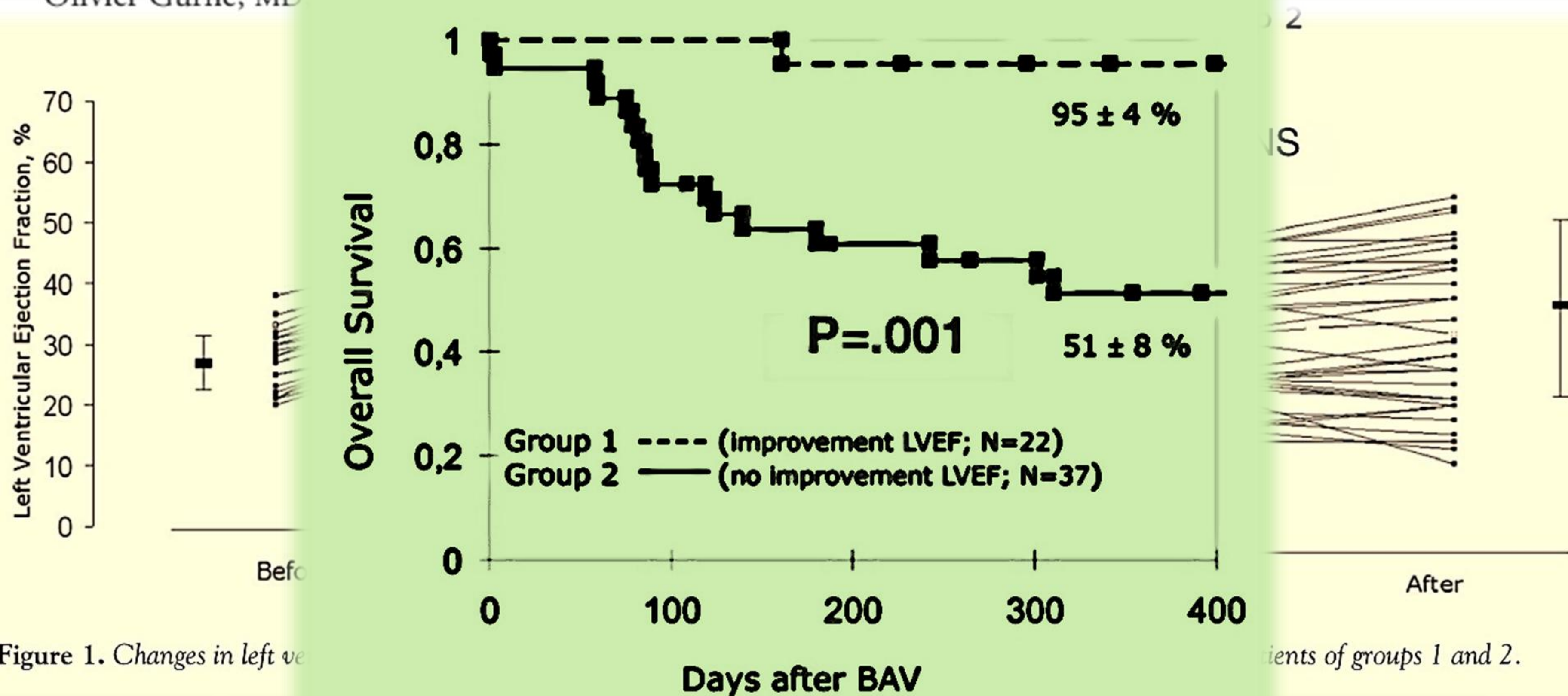


Figure 1. *Changes in left ve… …ients of groups 1 and 2.*

Figure 4. *Kaplan-Meier analysis shows the effect of left ventricular ejection fraction (LVEF) improvement 30 days after balloon aortic valvuloplasty (BAV) on 1-year mortality.*

When should we use stand-alone balloon valvuloplasty in the TAVI era?

Consensus

BAV come "BRIDGE"

a potenziali ulteriori interventi (AVR o TAVI)

PROCEDURA RESCUE

- **Pz in shock cardiogeno/emodinamica instabile a causa della stenosi aortica, che non possono essere sottoposti né alla AVR né alla TAVI**

- **La BAV rescue può permettere di:**

consentire un sufficiente recupero clinico/emodinamico/funzionale VS →

→ superare la fase critica

per poter considerare un trattamento definitivo successivo

When should we use stand-alone balloon valvuloplasty in the TAVI era?

Consensus

BAV come “BRIDGE”

a potenziali ulteriori interventi (AVR o TAVI)

- *fare la BAV nel modo più sicuro possibile*
  - *L’obiettivo non è portare il gradiente a zero*

- *non aspettare la ripresa dei sintomi/scompenso cardiaco*

Ristenosi dopo BAV

50% a sei mesi

80%
a 12-18 mesi

Ungheria
Croazia
Bosnia -
Erzegovina
SO
LC
VA
CO
BG
BS
MI
LO
PV
PC
PR
RE
MO
BO
FE
RA
FO
RN
SICILIA
Sicilia
Tunisia

il giornale italiano di

Cardiologia Invasiva

2•2014
APRILE-GIUGNO

ORGANO UFFICIALE DELLA SOCIETÀ ITALIANA DI CARDIOLOGIA INVASIVA - GISE
PERIODICO TRIMESTRALE A CARATTERE SCIENTIFICO DI EDUCAZIONE CONTINUA IN CARDIOLOGIA INVASIVA
Poste Italiane Spa - Spedizione in Abbonamento Postale - 70% DCB - Roma

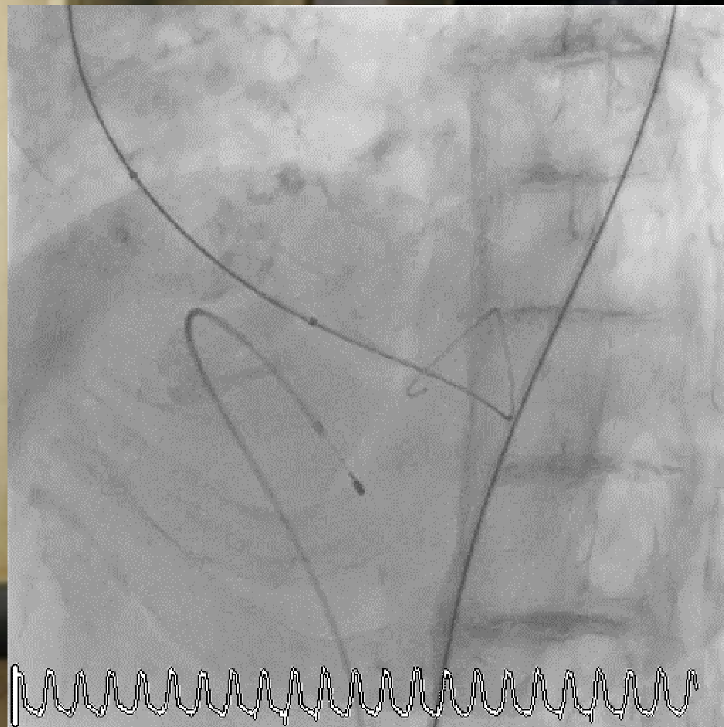
Dati di attività dei Laboratori di Emodinamica

gise 2013 (2012)	TAVI	BAV *non* seguite da impianto di protesi
TOT	1529 (1345)	1151 (943)

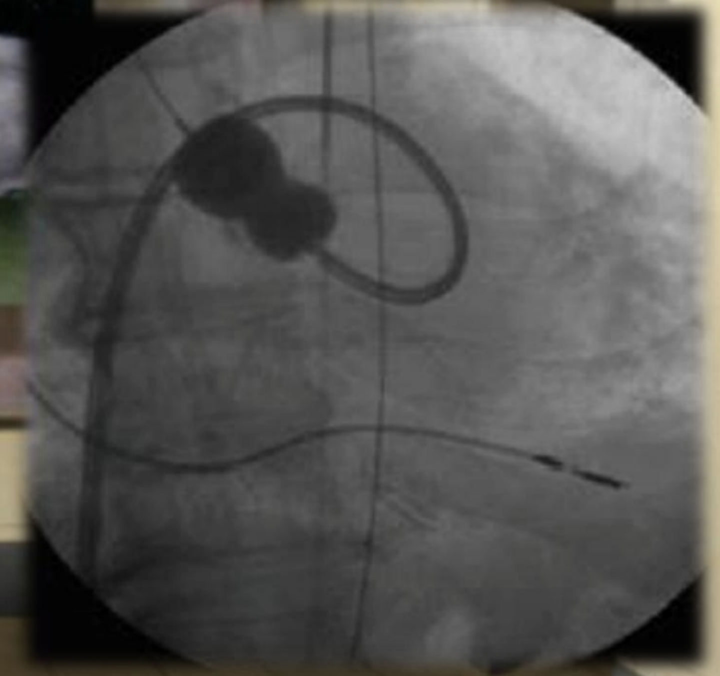
cenni di tecnica

APPROCCIO

Retrogrado
arteria femorale



Anterogrado
vena femorale
con puntura transettale



approccio retrogrado

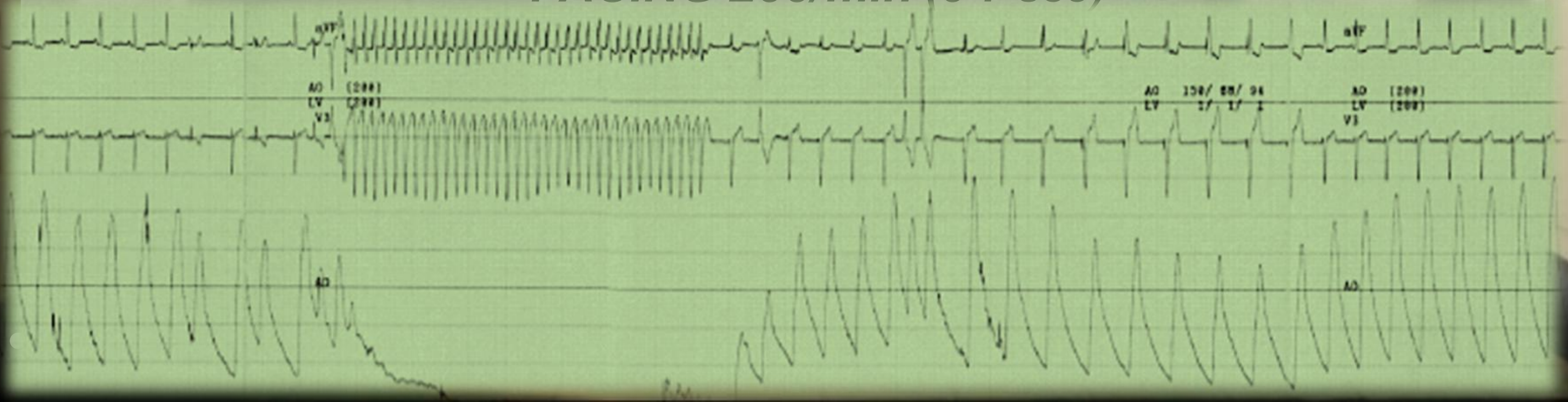
- Pre-emostasi con Perclose

- introduttore arterioso femorale:

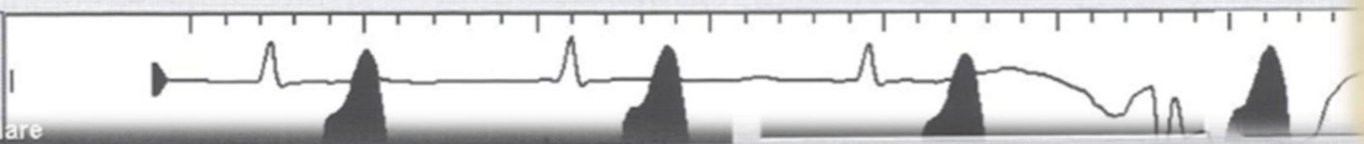
9 Fr per palloni fino a 20 mm, 10 Fr fino a 25 mm

- **Posizionamento PM in VDx per pacing rapido**

- Posizionamento pallone attraverso la valvola
- ***PACING 200/min (6-7 sec)***



gradiente medio transvalvolare



Misurazione gradiente: Misure area valvolare

50

Fase: Linea di base

Valvola: Aortica

GC: l/min Manuale

Gradiente 33,16 mmHg

Periodo eiezione sistolica: 21,27 s/minuto

Area valvolare cm²

Flusso valvolare ml/s

Manuale

<< < > >>

OK Annulla

Comando su

P1 LV

P2 AO

Comando in

200 180 160 140 120 100 80 60 40 20 0

AIM OF THE STUDY

Aortic balloon valvuloplasty:

Evaluation of safety and efficacy

in very elderly patients

not eligible for aortic valve replacement

Congresso Nazionale

Società Italiana

METHODS 1

108 PATIENTS

from 1st of January 2006 to 28th of February 2012 :

- Age ≥ 85
- Severe aortic stenosis according to
- Symptomatic aortic stenosis
  - Syncope
  - Heart failure
  - Angina
- Not eligible for AVR/TAVI

IN V

SAFET

Dott.

Dipartimento di Cardiologia

Ospe

Direttore dott. G. Piovaccari

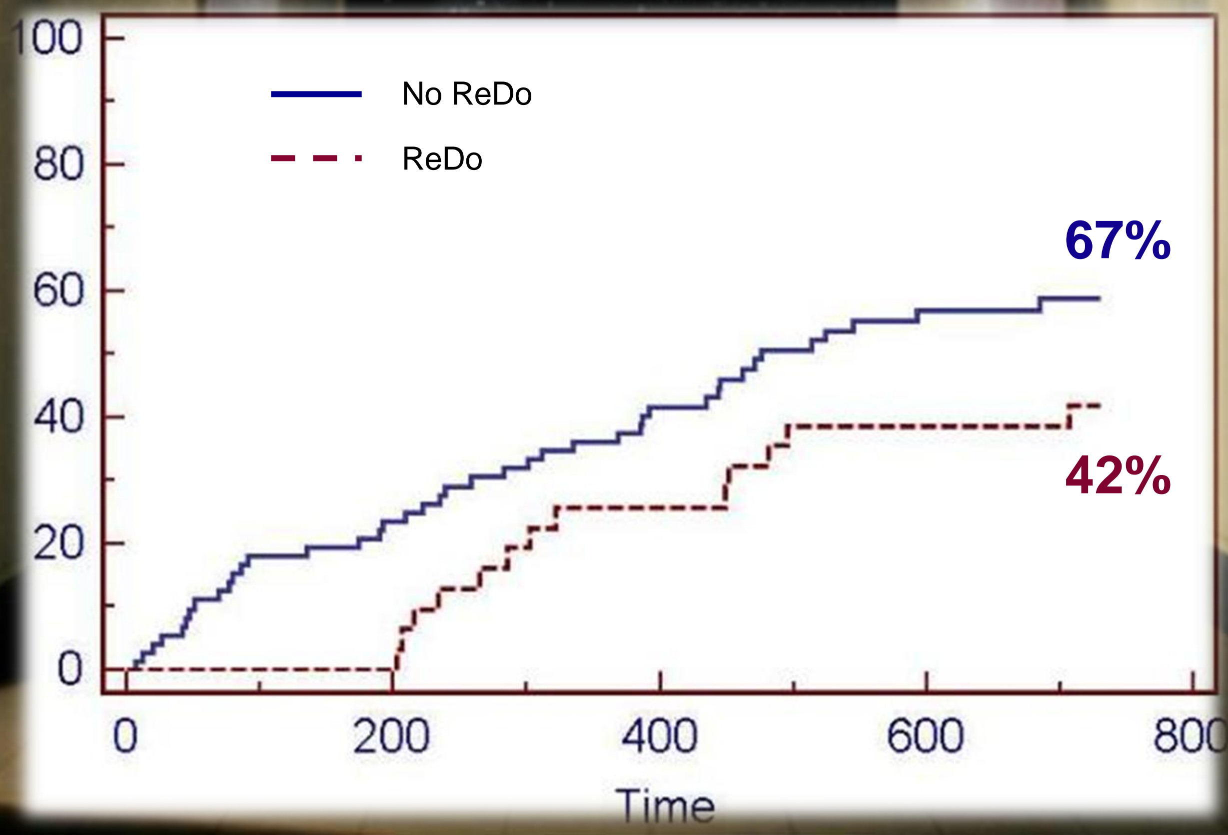
SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Unità Sanitaria Locale di Rimini

34º Congresso Nazionale Società Italiana di Cardiologia Invasiva

AORTIC BALLOON VALVULOPLASTY IN VERY ELDERLY: SAFETY AND EFFICACY

RESULTS

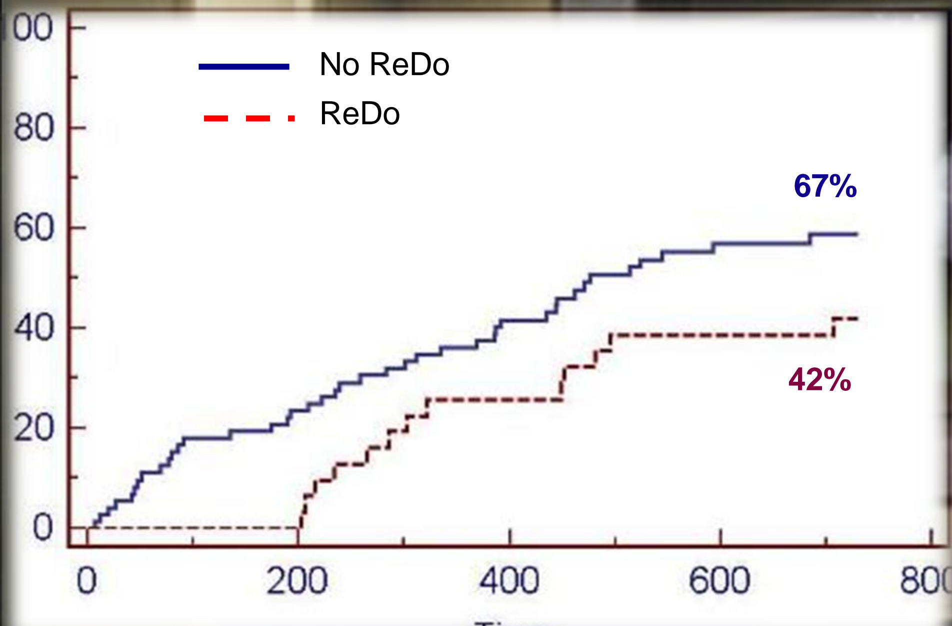
ReDo VS no ReDo at 2 ys MORTALITY

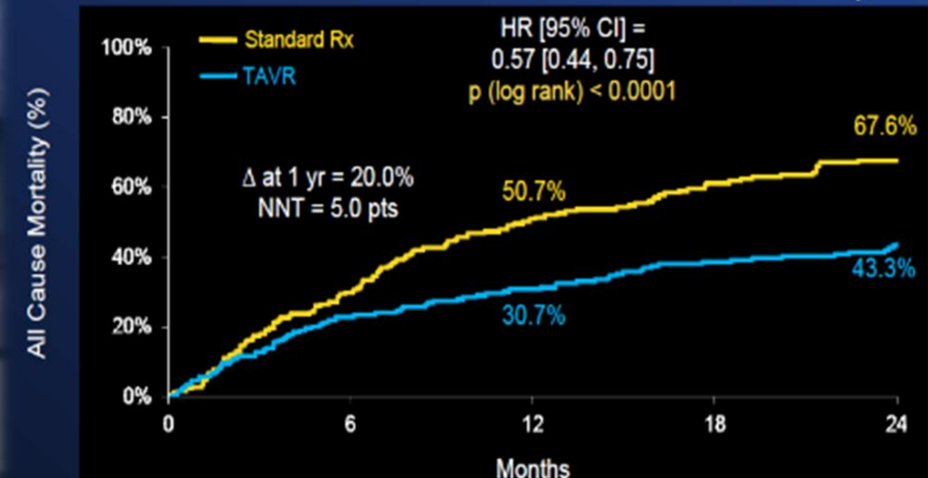


RESULTS

ReDo vs no ReDo
2 ys mortality

PARTNER study
2 ys mortality





AORTIC BALLOON VALVULOPLASTY
IN VERY ELDERLY:
SAFETY AND EFFICACY

Dott.ssa Federica Baldazzi

Dipartimento di Cardiologia
Ospedale Infermi, Rimini

Direttore dott. G. Piovaccari

THE PARTNER TRIAL

conclusioni

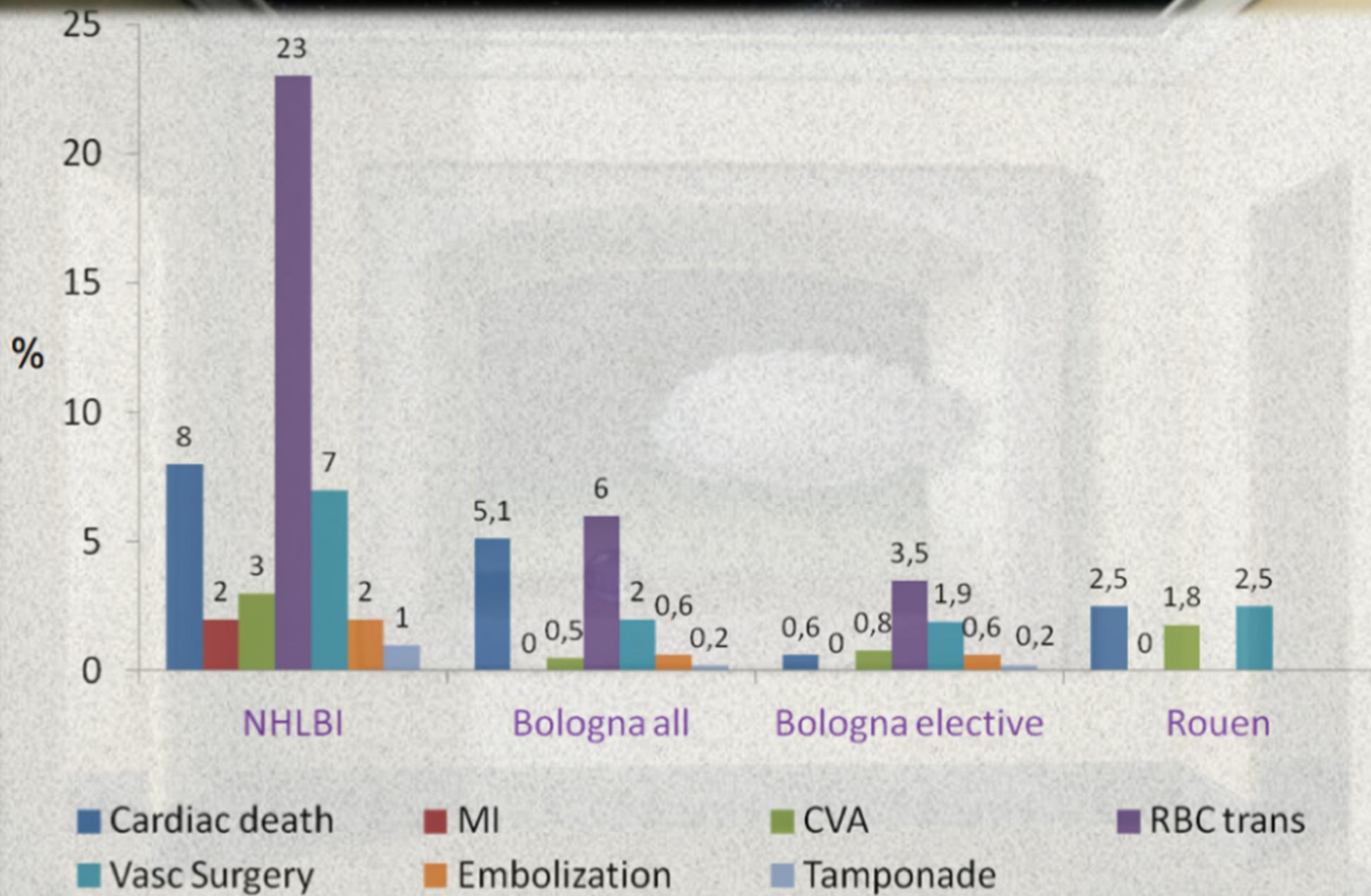
Anche in era TAVI
una quota di pazienti,
generalmente grandi anziani,
in cui AVR/TAVI non sono scelte percorribili,
rimane senza opzione terapeutica

La maggior parte di questi pz può trarre beneficio
da una procedura a basso costo
e sicura come la BAV ***(anche ripetuta)***
che garantisce un significativo miglioramento
emodinamico, clinico **e**
della qualità di vita

"BAV-bridge" può consentire una più accurata
selezione dei pz candidati
al trattamento definitivo

antonio nunziante
Gate
2012

grazie
per la vostra
attenzione
antonio nunziante
stanza segreta
2012


%
25
20
15
10
5
0
8
2
3
23
7
2
1
5,1
0
0,5
6
2
0,6
0,2
0,6
0
0,8
3,5
1,9
0,6
0,2
2,5
0
1,8
2,5
NHLBI
Bologna all
Bologna elective
Rouen
Cardiac death
MI
CVA
RBC trans
Vasc Surgery
Embolization
Tamponade

Aortic Valvuloplasty Complications

Emerging indications, in-hospital and long-term outcome of balloon aortic valvuloplasty in the transcatheter aortic valve implantation era

Congresso Nazionale
Società Italiana
di Cardiologia Invasiva

AORTIC BALLOON VALVULOPLASTY IN VERY ELDERLY: SAFETY AND EFFICACY

Dott.ssa Federica Baldazzi

Dipartimento di Cardiologia
Ospedale Infermi, Rimini

Direttore dott. G. Piovaccari

	All patients
Acute kidney injury*, % (n)	18.5 (77)
Class 3, % (n)	2.4 (10)
Aortic valve replacement, % (n)	1.7 (7)

PERI-PROCEDURE COMPLICATIONS	N (%)
Death	2 (1.8)
IMA/NSTEMI	1 (0.9)
Pericardial drainage	3 (2.7)
Hematoma	1 (0.9)
Blood Transfusion	1 (0.9)
Stroke	0
Arrhythmia	0

All Stroke (ITT)

Numbers at Risk

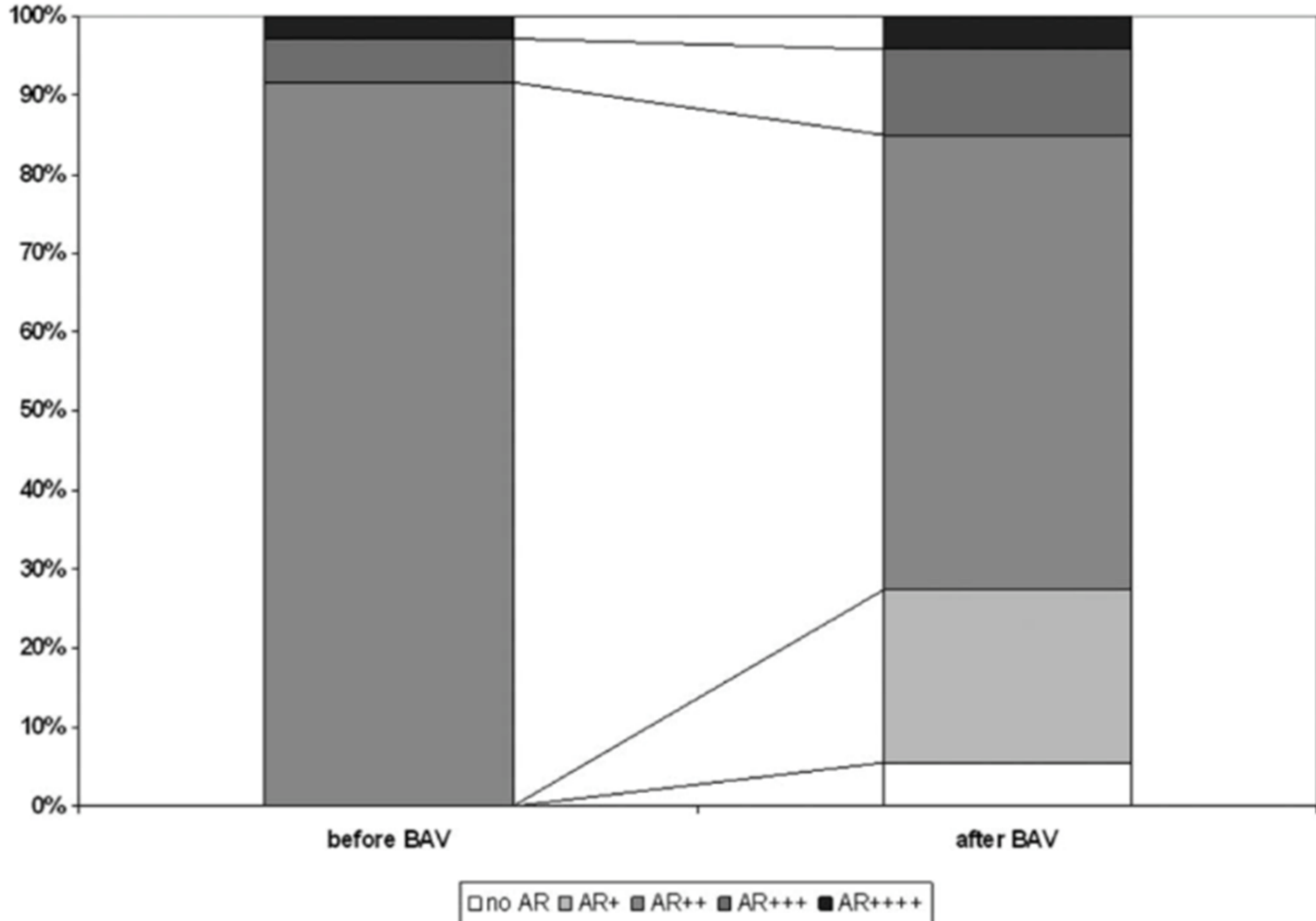
TAVR	179	128	116	105	79
Standard Rx	179	118	84	62	42

VALVULAR AND STRUCTURAL HEART DISEASES

Original Studies

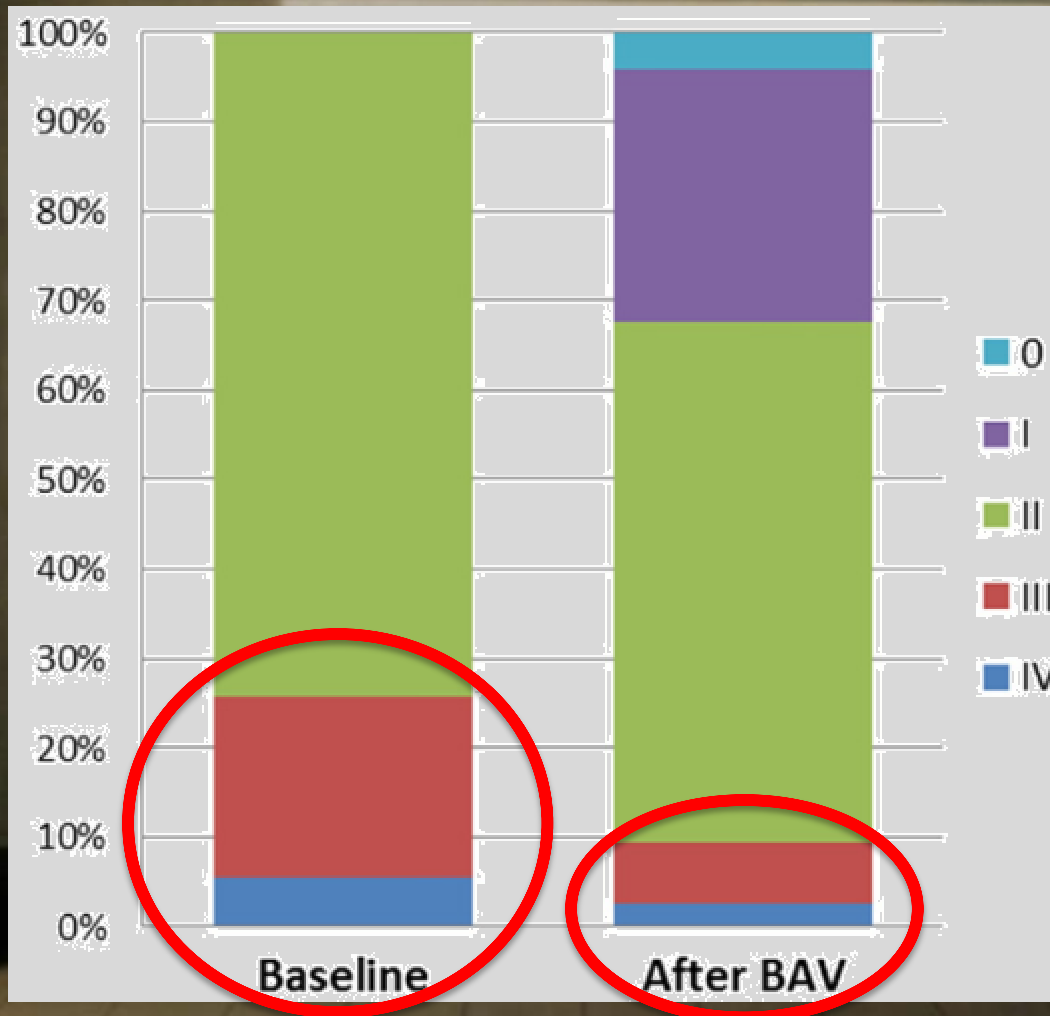
Is Balloon Aortic Valvuloplasty Safe in Patients WIth Significant Aortic Valve Regurgitation?

Francesco Saia,* MD, PhD, Cinzia Marrozzini, MD, Cristina Ciuca, MD,



Saia et al., Cath Card Int 2012; 79:315-321

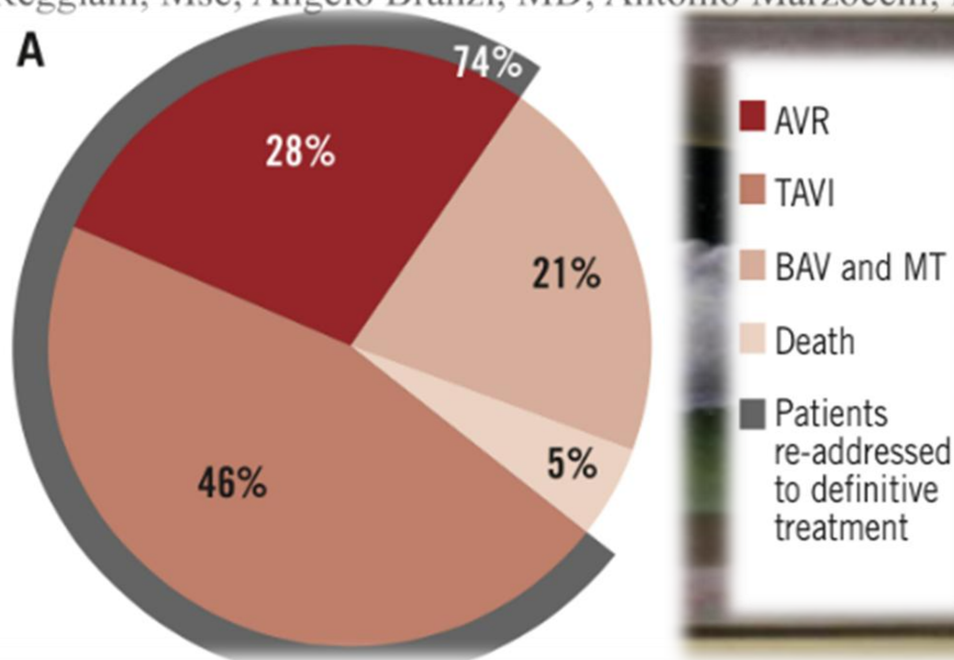
Changes in Mitral Regurgitation after BAV



Maluenda G et al. *Am J Cardiol* 2011; 108:1777-82

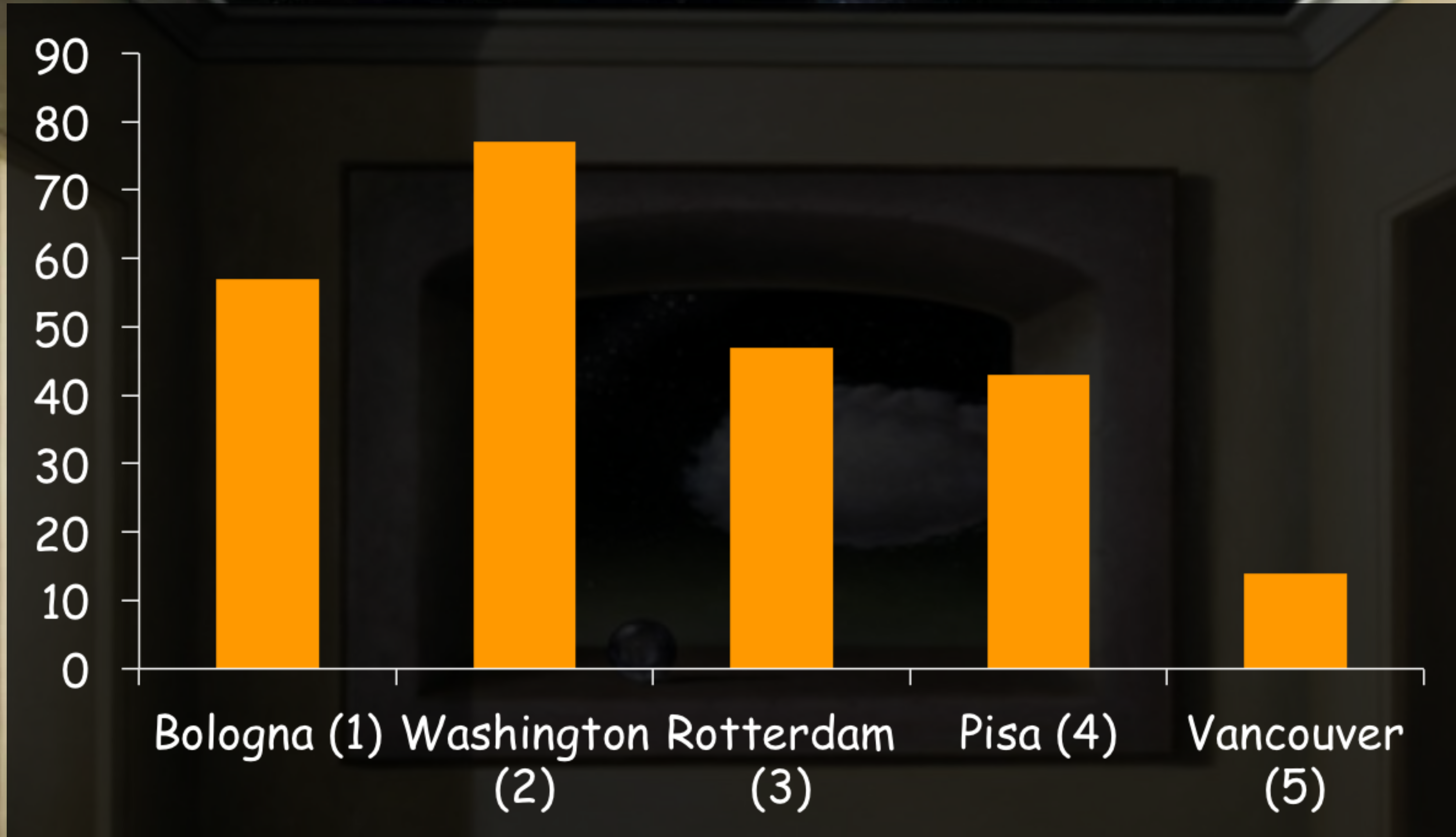
The role of percutaneous balloon aortic valvuloplasty as a bridge for transcatheter aortic valve implantation

Francesco Saia*, MD, PhD; Cinzia Marrozzini, MD; Carolina Moretti, MD; Cristina Ciuca, MD; Nevio Taglieri, MD; Barbara Bordoni, MD; Gianni Dall'Ara, MD; Laura Alessi, MD; Valerio Lanzillotti, MD; Maria Letizia Bacchi-Reggiani, Msc; Angelo Branzi, MD; Antonio Marzocchi, MD EuroIntervention 2011;7:723-729



Overall, 36 patients (46%) were finally accepted for TAVI, and 22 (28%) were even deemed eligible for surgical AVR. Sixteen patients (21%) did not exhibit any improvement and were addressed to medical therapy.

Pz indirizzati a TAVI, non elegibili registri



1. Saia F. et al. *J Cardiovasc Med* 2010;11:727-32

2. Ben-Dor I et al. *Circulation* 2010;122:S37-42

3. Otten AM et al. *Eurointervention* 2008;4:250-55

4. De Carlo M et al. *Eurointervention* 2010;6:168-74

5. Lauck S et al. *Eur J Cardiovasc Nurs 2014;13:177–184*

il giornale italiano di
Cardiologia Invasiva

2•2014 APRILE-GIUGNO

ORGANO UFFICIALE DELLA SOCIETÀ ITALIANA DI CARDIOLOGIA INVASIVA - GISE

PERIODICO TRIMESTRALE A CARATTERE SCIENTIFICO DI EDUCAZIONE CONTINUA IN CARDIOLOGIA INVASIVA
Poste Italiane Spa - Spedizione in Abbonamento Postale - 70% DCB - Roma

Dati di attività

gise 2014 (2013)	TAVI	VAP non seguite da impianto di protesi
lombardia	(402)	(109)

JACC: CARDIOVASCULAR INTERVENTIONS
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http://dx.doi.org/10.1016/j.jcin.2014.08.015

Outcomes of Inoperable Symptomatic Aortic Stenosis Patients Not Undergoing Aortic Valve Replacement

Insight Into the Impact of Balloon Aortic Valvuloplasty From the PARTNER Trial (Placement of AoRtic TraNscathetER Valve Trial)

Samir Kapadia, MD,* William J. Stewart, MD,* William N. Anderson, PhD,† Vasilis Babaliaros, MD,‡ Ted Feldman, MD,§ David J. Cohen, MD, MSc,‖ Pamela S. Douglas, MD,¶ Raj R. Makkar, MD,# Lars G. Svensson, MD, PhD,* John G. Webb, MD,** S. Chiu Wong, MD,†† David L. Brown, MD,‡‡ D. Craig Miller, MD,§§ Jeffrey W. Moses, MD,‖‖ Craig R. Smith, MD,‖‖ Martin B. Leon, MD,‖‖ E. Murat Tuzcu, MD*

CONCLUSIONS BAV improves functional status and survival in the short term, but these benefits are not sustained. BAV for aortic stenosis patients who cannot undergo aortic valve replacement is a useful palliative therapy. (THE PARTNER TRIAL: Placement of AoRTic TraNscathetER Valve Trial; NCT00530894) (J Am Coll Cardiol Intv 2015;8:324–33) © 2015 by the American College of Cardiology Foundation.

CLINICIAN UPDATE

Hideiko et al, circulation 2007; 115:e334-e338

Percutaneous Balloon Aortic Valvuloplasty Revisited

Time for a Renaissance?

Hideiko Hara, MD; Wesley R. Pedersen, MD; Elena Ladich, MD; Michael Mooney, MD; Renu Virmani, MD; Masato Nakamura, MD; Ted Feldman, MD; Robert S. Schwartz, MD

200

150

2007

2005-07

CE mark commercialization

International TF Feasibility Studies

1987

1985

Post-mortem studies of intra-valvular stenting Sketches of stented valve

Concept of « stented valve », to rule out post-BAV valvular restenosis

F.I.M. Balloon Aortic Valvuloplasty

1991 1993 1995 2003 2005 2007 2009

European Heart Journal (2005) 26, 2714–2720
doi:10.1093/eurheartj/ehi471

Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery?

Berna ... ye[3],
Pilar ... an[1]